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LAWSON AND WEITZEN LLP

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09/808,002

Response to Office Action of November 17, 2005

Via facsimile 571-273-8300

Date of Deposit: March 16, 2006

Attorney Docket Number US 010387

Remarks

Claims 1 and 23 are here amended. Support for amendment of claim 1 is found in the specification as filed, ¶ [0015], on pages 4-5. Support for amendment of claim 23 is found in this claim as previously presented.

Claims 1-23 are pending in the application. No new matter has been added, and no new material presented that would necessitate an additional search on the part of the Examiner.

Issues under 35 U.S.C. §112 ¶2

The Office Action on page 2, ¶3 rejects claim 22 as lacking proper antecedent basis. Applicants assert that claim 22, line 2, stating "...the medical characteristic...", contains proper antecedent basis for this phrase in claim 8, and respectfully request further explanation regarding this rejection.

Claims as amended comply with 35 U.S.C. §101

The Office Action on page 2, ¶4 rejects claims 1-7 and 23 under 35 U.S.C. §101 as directed to non-statutory subject matter.

Claim 1 as here amended is directed to a computer readable medium downloaded to a machine to supply a means for providing at least one predetermined field arranged within the medical report and a means for automatically inserting data representative of a medically relevant characteristic into at least one predetermined field when the report generator produces a medical report. The machine is a general purpose computer, a personal computer, or a specialized report generator downloaded with the computer-readable medium to perform the report generator functions.

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Applicants assert that claim 1 as here amended is directed to a machine having well-known components.

Claim 23 as here amended is directed to the computer readable medium being tangibly embodied within the computer, and structurally related to the computer, by downloading a set of computer instructions stored on a computer-readable medium to carry out the method of electronically generating the medical report.

Claim 23 as here amended is directed to a computer-readable medium that is downloaded on a computer. The computer is therefore changed functionally, which is a tangible result.

Claims 2-7 depend directly on claim 1 and therefore incorporate the subject matter of this claim as here amended. Applicants assert that claims 1-7 and 23 as here amended conform to 35 U.S.C. §101, and respectfully request that this rejection be withdrawn.

Issues under 35 U.S.C. §103(a)

Prior to analyzing the art cited in the Office Action, Applicants believe that a brief description of the subject matter of independent claim 1 as here amended and independent claims 8 and 15 would be of use to the Examiner.

Claim 1 as here amended is directed to a report generator for automatically and electronically generating a computer-readable medical report. The report generator includes a way of providing at least one predetermined field arranged within the medical report, which includes data representative of a medically relevant characteristic. The report generator also includes a way of automatically inserting data representative of a medically relevant characteristic into at least one predetermined field upon report generation. The

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means for providing and the means for inserting are embodied in a computer readable medium, which is downloaded for processing into a machine which is a general purpose computer, a personal computer, or a specialized report generator.

Claim 8 is directed to a system for electronically generating a medical report. The system includes a report generator for generating an electronic medical report, which has at least one predetermined field to hold data representative of medical characteristic. The report generator includes an interface for receiving data input. Upon automatic generation of the medical report, a measured value defining a medical characteristic is inserted into the field so that the generated medical report is included with the medical characteristic.

Claim 15 is directed to a method of electronically generating a medical report including a plurality of fields representative of a plurality of medical conditions, with steps of electronically selecting a medical condition for inclusion within the medical report, and automatically inserting a measurement corresponding to the selected medical condition when the medical report is generated so that the measurement replaces the field.

The Office Action on page 4, ¶6 rejects claims 1-2, 4-9, 15-16 and 18-22 under 35 U.S.C. §103(a) as being unpatentable over Applicants' background of the invention (pages 1-2 of Applicants' specification) in view of Coli et al. (U.S. patent number 6,018,713, issued January 25, 2000).

Coli et al., U.S. patent number 6,018,713, issued January 25, 2000

Coli et al. taken as a whole shows systems for ordering medical tests on-line in a health care network, i.e., a network that would be used by remotely located medical personnel, and recording and reporting the test results, and collecting and statistically

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analyzing test results. See Coli et al., column 1, lines 9-14. It is simply a communication tool for remote locations in a health network.

Coli et al. fails to teach or suggest a report generator for automatically and electronically generating a computer-readable medical report that has means for automatically inserting data in a predetermined field. Rather, Coli et al. shows a network for ordering tests and reporting results of these tests. See Coli et al., claim 1. Coli et al. thus fails to teach or suggest any system or method for automatically inserting data of a medically relevant characteristic into a predetermined field upon generating a medical report, as is the subject matter of claim 1 as here amended and claims 8 and 15.

Applicants' background of the invention clearly points out substantial limitations of the related prior art, a need for which claims 1, 8 and 15 are addressed. Applicants' specification states:

In a medical report of the related art, it is possible to enter in a free text diagnosis that may contain a measurement value. The free text can then be manually modified. However, re-performing an automatically calculated measurement does not automatically change the free text portion of the report. Thus, measurements changed in a measurement section of the report may be inconsistent with the free text in the interpretation section of the report. In addition, the process of free text entry is error prone and may result in an incorrect measurement value being transcribed. [See Applicants' specification as filed, ¶ [0007], page 1; emphases added]

First, Applicants assert that Applicants' background addresses the substantial problems in the prior art and lack of teaching in that prior art, evidenced by the quotation above. The quotation above clearly shows that Applicants at the time the application was filed clearly asserted that the prior art fails to teach or suggest a means for automatically changing the free text portion of the report. Second, Applicants' background description is not proper prior art. Third, the combination of this background and Coli et al. fails to teach

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or suggest all of the elements of claims 1, 8 and 15.

In contrast to the prior art including Coli et al., Applicants' claim 1 as here amended and claims 8 and 15 is directed to means for providing at least one predetermined field in a medical report that includes data representative of a medically relevant characteristic, and means for automatically inserting data representative of a medically relevant characteristic into at least one predetermined field upon report generation.

Claims 2, 4-7, 9, 16 and 18-22 which depend directly on claims 1, 8 and 15 and contain additional subject matter are likewise not obvious in view of the cited reference and Applicants' own background. Applicants respectfully request that rejection of claims 1-2, 4-9, 15-16 and 18-22 be withdrawn.

The Office Action on page 7, ¶7 rejects claims 3, 10 and 17 under 35 U.S.C. §103(a) as being unpatentable over Applicants' background of the invention (pages 1-2 of Applicants' specification) in view of Coli et al. (U.S. patent number 6,018,713, issued January 25, 2000) and further in view of Stoodley (U.S. patent number 6,611,846, issued August 26, 2003):

Stoodley, U.S. patent number 6,611,846, issued August 26, 2003

Stoodley taken as a whole shows a method of analyzing comprehensive medical patient data through a medical database. See Stoodley, column 1, lines 8-10. Stoodley shows a medical data analysis system that includes a database that allows for clinical auditing and research and/or presentation activities with patient data, and a method of using the system. Ibid, column 6, lines 3-6.

Stoodley fails to cure the defects of Coli et al. in combination with Applicants'

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specification, because Stoodley, like the cited prior art, fails to teach or suggest any means for automatically inserting data of a medically relevant characteristic into a predetermined field upon generating a medical report.

In contrast to Stoodley, claim 8 is directed to a system for electronically generating a medical report. In claim 8, when the medical report is automatically generated, a measured value defining a medical characteristic is inserted into a predetermined field. Stoodley fails to teach or suggest a system for automatically and electronically generating a medical report, or for inserting data into a predetermined field upon automatically generating a medical report. Therefore Stoodley fails to cure any of the defects of Coli et al. in combination with Applicants' own background with respect to both claims 1 and 8.

Claim 15 is directed to a method of electronically generating a medical report where a measurement corresponding to a selected medical condition is automatically inserted when the medical report is generated so that the measurement replaces the field.

In contrast, Stoodley shows only a method of analyzing patient data. Stoodley fails to teach or suggest a method of electronically generating a medical report with measurements automatically inserted when the report is generated. Therefore Stoodley fails to cure the defects of Coli et al. in combination with Applicants' own background with respect to claim 15.

Each of claims 3, 10 and 17 depends directly from independent claim 1, 8 or 15, respectively, and therefore incorporates all of the subject matter of the respective independent claim. The factual analysis above shows that claims 1, 8 and 15 are not obvious in view of the combination of Coli et al. and Stoodley alone or in combination with

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Applicants' own background. As Stoodley fails to cure the defects of Coli et al. with respect to claims 1, 8 and 15, therefore claims 3, 10 and 17 are not obvious in view of the combination of Coli et al. and Stoodley alone or in combination with Applicants' own background.

Legal analysis

Whether an invention would have been obvious under 35 U.S.C. §103(a) is a legal conclusion based on underlying findings of fact. *In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000).

The *Manual of Patent Examining Procedure* states: "[t]o establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure." [emphases added] *Manual of Patent Examining Procedure* §2142 (8th Ed. Rev.2, May 2, 2004); *In re Vaack*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Applicants respectfully traverse the rejection, and show that the facts of the case and the relevant case law indicate that the invention would not have been obvious to one of ordinary skill in the art, at the time the application was filed, for the following reasons.

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First, to establish a *prima facie* case for obviousness of a claimed invention, all of the claim limitations must be taught or suggested by the prior art. *Manual of Patent Examining Procedure*, §2143.03, p. 108 (8th Ed. Rev.2, May 2, 2004); *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

To reach a proper determination under 35 U.S.C. §103, the examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made. *Manual of Patent Examining Procedure*, §2142, p. 104 (8th Ed. Rev.2, May 2, 2004). In view of factual information, the examiner makes a determination of whether the claimed invention "as a whole" would have been obvious at that time to that person. *Id.*

Knowledge of Applicants' disclosure must be put aside in reaching this determination, and kept in mind only to determine the "differences," conduct the search and evaluate the "subject matter as a whole" of the invention. *Id.* Impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art. *Id.*

Most if not all inventions arise from a combination of old elements. Courts consistently hold that employing hindsight and using the present application as a blueprint to pick and choose references to reconstruct the invention is impermissible. *In re Kotzab*, 217 F.3d 1365, 1369; 55 U.S.P.Q.2d 1313 (Fed. Cir. 2000). Thus, every element of a claimed invention may often be found in the prior art. *Id.* at 1367-1370. However, identification in the prior art of each individual part claimed is insufficient to defeat patentability of the whole claimed invention. *Id.* at 1370. Rather, to establish obviousness based on a

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combination of the elements disclosed in the prior art in the absence of any hindsight, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant. *Id.* The teaching or suggestion, not merely to make the claimed combination, but also of a reasonable expectation of success, must both be found in the prior art, and not based on applicant's disclosure. *In re Vaack*, 947 F.2d 488; 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

An element of the record generator of claim 1 is means for providing at least one predetermined field arranged within a medical report that includes data representative of a medically relevant characteristic, and means for automatically inserting data representative of a medically relevant characteristic into at least one predetermined field upon report generation.

Claim 1 is not obvious because none of the cited references, alone or in combination, teach or suggest a report generator for automatically and electronically generating a computer-readable medical report that has means for automatically inserting data in a predetermined field. Claims 2-7 depend from claim 1 and therefore include the subject matter of claim 1 of a means for automatically inserting data. Stoodley fails to cure the defects of Coli et al. with respect to at least this claim element because this reference does not teach or suggest automatically inserting data into a predetermined field upon generation of a medical report.

In conclusion with respect to claims 1-7, none of the cited primary references show the element of claim 1 of a means for automatically inserting data representative of a medically relevant characteristic into at least one predetermined field upon report

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generation. Therefore, under the legal criteria discussed above, analysis of the underlying facts of the present pending claims show that the prior art does not teach or suggest all the subject matter of the claims of the present invention. Therefore, the Office Action fails to establish a *prima facie* case that claim 1 of the present invention is obvious. Claims 2-7 that depend directly from claim 1 and incorporate the subject matter of claim 1 and contain additional subject matter also are not obvious in light of the cited references.

Claim 8 is directed to subject matter including that upon automatic generation of the medical report, a measured value defining a medical characteristic is inserted into the field so that the generated medical report is included with the medical characteristic.

Claim 8 is not obvious because none of the cited references, alone or in combination, teach or suggest a system for electronically generating a medical report where upon automatic generation of the medical report, a measured value defining a medical characteristic is inserted into the field so that the generated medical report is included with the medical characteristic. Claims 9-14 and 22 depend from claim 8 and therefore include the subject matter of claim 8 of a means for automatically inserting data. Stoodley fails to cure the defects of Coli et al. with respect to at least this claim element because this reference does not teach or suggest inserting a measured value into a predetermined field upon automatically generating a medical report.

In conclusion with respect to claims 8-14 and 22, none of the cited primary references show the element of claim 8 of a system for electronically generating a medical report where a measured value is inserted into a predetermined field upon automatic generation of the medical report. Therefore, under the legal criteria discussed above, analysis

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of the underlying facts of the present pending claims show that the prior art does not teach or suggest all the subject matter of the claims of the present invention. Therefore, the Office Action fails to establish a *prima facie* case that claim 8 of the present invention is obvious. Claims 9-14 and 22 that depend directly from claim 8 and incorporate the subject matter of claim 8 and contain additional subject matter also are not obvious in light of the cited references.

An element of the method of claim 15 is that a measurement corresponding to the selected medical condition is automatically inserted when the medical report is generated whereby the measurement replaces the field.

Claim 15 is not obvious because none of the cited references, alone or in combination, teach or suggest a method of electronically generating a medical report that includes automatically inserting a measurement corresponding to a selected medical condition when the medical report is generated so that the measurement replaces the field. Claims 16-21 and 23 depend from claim 15 and therefore include the subject matter of a means for automatically inserting data. Stoodley fails to cure the defects of Coli et al. with respect to at least this claim element because this reference does not teach or suggest automatically inserting a data upon generation of a medical report.

In conclusion with respect to claims 16-21 and 23, none of the cited references show the element of claim 15 of a method of electronically generating a medical report that includes automatically inserting a measurement corresponding to a selected medical condition upon generating the report. Therefore, under the legal criteria discussed above, analysis of the underlying facts of the present pending claims show that the prior art does not

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teach or suggest all the subject matter of the claims of the present invention. Therefore, the Office Action fails to establish a *prima facie* case that claim 15 of the present invention is obvious. Claims 16-21 and 23 that depend directly from claim 15 and incorporate the subject matter of claim 15 and contain additional subject matter also are not obvious in light of the cited references.

For these reasons, Applicants assert that the present claims comply with 35 U.S.C. §103(a), and respectfully request that rejection of claims 1-22 under 35 U.S.C. §103(a) be withdrawn.

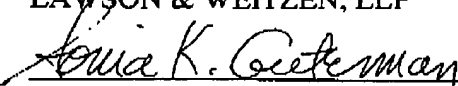
Summary

On the basis of the foregoing reasons, Applicants respectfully submit that the pending claims are in condition for allowance, which is respectfully requested.

If there are any questions regarding these remarks, the Examiners are invited and encouraged to contact Applicants' representative at the telephone number provided.

Respectfully submitted,

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